REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated November 16, 2007 (hereinafter, the "Office Action").

It is Applicants' understanding that examination of this matter is now being handled by an Examiner other than former Examiner Susan Ungar. Applicants set forth below reasons in support of the patentability of the pending claims. Should the current Examiner be inclined to disagree, Applicants respectfully request the courtesy of a telephone interview and the issuance of a non-final Office Action in view of the same.

Regarding the Office Action, it is alleged that Claims 12, 19-21, 24-26 and 31-35 stand rejected under 35 U.S.C. §112, first paragraph, on the following basis:

> [B]ecause the specification, while being enabling for a method of treating a solid, vascularized tumor with a chemotherapeutic agent, cisplatin (CIS), carboplatin, mitomycin does not reasonably provide enablement for a method of treating a solid vascularized tumor comprising administering erythropoietin (EPO), in an amount effective to enhance suppression of endothelial growth associated with administration of cisplatin, carboplatin, mitomycin, in a dosage range of 750 U/kg to 2000 U/kg prior to administering cisplatin, carboplatin or mitomycin.

Office Action, page 2.

The Office Action further asserts the following:

> It is noted that although Applicant presents convincing objective evidence in (a) the Sigounas Declaration submitted July 15, 2003 that demonstrates that administration of 60 U/kg EPO to mice prior to administration of CIS resulted in effective therapeutic treatment of a solid vascularized tumor in an appropriate animal model, (b) the Sigounas Declaration submitted November 2, 2005 in combination with the Sigounas Declaration of November 30, 2006 that demonstrates that administration of 60 U/kg EPO prior to administration of CIS, carboplatin or mitomycin resulted in effective therapeutic treatment of a solid vascularized tumor in an appropriate animal model, none of these declarations are commensurate in scope with the instantly claimed invention requiring a dosage in the range of 750 Units per kilogram to 2000 Units per kilogram EPO. . . . Clearly, given that the mice weigh 15-20 grams, administering 60 U/kg to these mice would result in the administration of a dose of .9 U/kg and a dose of 1.2 U/kg EPO, respectively. This dose is clearly not within the range instantly claimed. . . . Further, even

> if one were to find that a typographical error had occurred and that each mouse is administered 60 U of EPO, a dose of 750 U/kg would require the administration of a dose of 11.25 Units and a dose of 15 Units fro mice 15 and 20 grams, respectively. . . . Submission of a Declaration with objective evidence, demonstrating that the units administered per mouse are within the claimed range would obviate the instant rejection.

Office Action, pages 5-7.

In response to the Office Action, Applicants submit concurrently herewith a further Declaration Under 37 C.F.R. §1.132 of George Sigounas, Ph.D. (hereinafter, "the Sigounas Declaration"). The Sigounas Declaration indicates that the 60 U/kg dosage referenced in the previous Sigounas Declarations is a typographical error. Instead, the correct dosage was 60 Units EPO per mouse. As noted in the Sigounas Declaration, mice received in the East Carolina animal facility weighed approximately 15-20 grams. These animals were kept in the animal facility for at least two weeks prior to experimentation. During this time, the animals gained weight. Accordingly, based upon an appropriate conversion factor, a 30 g mouse injected with 60 U of EPO received approximately 2000 U/kg EPO. As further noted in the Sigounas Declaration, data from both the *in vitro* and *in vivo* studies convey to one skilled in the art that the 750 Units per kilogram to about 2,000 Units per kilogram dosage range recited in the claims is ascertainable from the information provided in the specification and is within the expected effective range for treating a solid vascularized tumor as presently claimed.

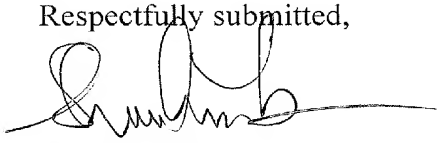
Thus, Applicants respectfully submit that one of skill in the art can practice the invention without undue experimentation where the key word is "undue," not "experimentation." Case law holds that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (quoting *In re Jackson*, 217 USPQ 804, 807 (CCPA 1982)). In view of the specification, *in vitro* and *in vivo* studies and established methods and conversion factors for determining EPO dosage in animal subjects, Applicants respectfully submit that any experimentation, if any, required to practice the invention is merely routine.

Based upon at least the foregoing, Applicants respectfully submit that the invention is fully enabled for the scope of the invention as presently claimed. Accordingly, Applicants respectfully request that the rejection of the Claims 12, 19-21, 24-26 and 31-35 under 35 U.S.C. § 112, first paragraph, as lacking enablement, be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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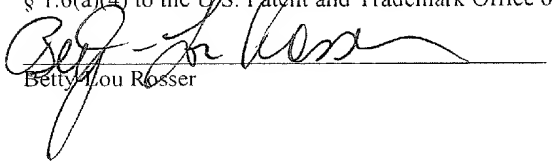

Betty Lou Rosser